



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2013-0013]

Monsanto Company and Forage Genetics International (FGI); Availability of Petition for Determination of Nonregulated Status of Genetically Engineered Alfalfa

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) has received a petition from the Monsanto Company and Forage Genetics International (FGI) seeking a determination of nonregulated status of alfalfa designated as event KK179, which has been genetically engineered to express reduced levels of guaiacyl lignin. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are making the Monsanto Company and FGI petition available for review and comment to help us identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to

<http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0013-0001>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2013-0013, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0013> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

The petition is also available on the APHIS Web site at http://www.aphis.usda.gov/brs/aphisdocs/12_32101p.pdf.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the petition, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or

produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 12-321-01p) from the Monsanto Company and Forage Genetics International (FGI) seeking a determination of nonregulated status of alfalfa designated as event KK179, which has been genetically engineered to express reduced levels of guaiacyl lignin (G lignin), a major subunit component of total lignin, as compared to conventional alfalfa at the same stage of growth. This reduction in G lignin leads to reduced accumulation of total lignin in alfalfa forage, the principal feed product derived from alfalfa. The petition states that this alfalfa event is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the petition, the Monsanto Company and FGI have developed event KK179 (Medicago sativa L.) for reduced levels of G lignin through the suppression of caffeoyl CoA 3-O-methyltransferase (CCOMT), a key enzyme in the lignin biosynthetic pathway. Event KK179 was produced by insertion of CCOMT gene segments, derived from alfalfa, assembled to form an inverted repeat DNA sequence. The inverted repeat sequence produces double-stranded RNA which suppresses endogenous CCOMT gene expression via the RNA interference pathway. Suppression of the CCOMT gene expression leads to lower CCOMT protein

expression resulting in reduced synthesis of G lignin subunit compared to conventional alfalfa at the same stage of growth. The reduction in G lignin subunit synthesis leads to reduced accumulation of total lignin, measured as acid detergent lignin. Event KK179 is currently regulated under 7 CFR part 340. Interstate movement and field tests of event KK179 have been conducted under notifications acknowledged by APHIS.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are used by APHIS to determine if the new variety poses a plant pest risk.

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the Federal Register providing 60 days for public comment for petitions for a determination of nonregulated status. On March 6, 2012, we published in the Federal Register (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice¹ describing our process for soliciting public comment when considering petitions for determinations of nonregulated status for GE organisms. In that notice we indicated that APHIS would accept written comments regarding a petition once APHIS deemed it complete.

In accordance with § 340.6(d) of the regulations and our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. The petition is available for public

¹ To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

review, and copies are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above.

We are interested in receiving comments regarding potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. We are particularly interested in receiving comments regarding biological, cultural, or ecological issues, and we encourage the submission of scientific data, studies, or research to support your comments. We also request that, when possible, commenters provide relevant information regarding specific localities or regions as alfalfa growth, crop management, and crop utilization may vary considerably by geographic region.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information; any substantive issues identified by APHIS based on our review of the petition and our evaluation and analysis of comments will be considered in the development of our decisionmaking documents.

As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS prepares a plant pest risk assessment to assess its plant pest risk and the appropriate environmental documentation--either an environmental assessment (EA) or an environmental impact statement (EIS)--in accordance with the National Environmental Policy Act (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. For petitions for which APHIS prepares an EA, APHIS will follow our published process for soliciting public comment (see footnote 1) and publish a separate notice in the Federal Register announcing the availability of APHIS' EA and plant pest

risk assessment. Should APHIS determine that an EIS is necessary, APHIS will complete the NEPA EIS process in accordance with Council on Environmental Quality regulations (40 CFR part 1500-1508) and APHIS' NEPA implementing regulations (7 CFR part 372).

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 17th day of April 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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